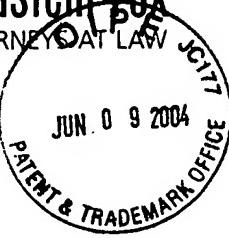




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\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice Limited to Federal Agencies

June 9, 2004

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Art Unit 1632

Re: U.S. Utility Patent Application  
Application No. 10/716,619; Filed: November 20, 2003  
For: Hematopoietic Cell Culture Nutrient Supplement  
Inventors: Daley *et al.*  
Our Ref: 0942.3750002/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. Listing of the cited documents on Form PTO-1449 (15 sheets);
3. Copies of seven (7) cited documents (AL2, AS4, AS7, AS13, AR14, AS14 and AT14); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN &amp; FOX P.L.L.C.

Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

FRC/shr  
Encls.

SKGF\_271963.1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Daley *et al.*

Appl. No.: 10/716,619

Filed: November 20, 2003

**For: Hematopoietic Cell Culture  
Nutrient Supplement**

Confirmation No.: 6354

Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket: 0942.3750002/RWE/FRC

**Information Disclosure Statement under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97, and 1.98. All documents except for AL2, AS4, AS7, AS13, and AR14 to AT14 were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 08/792,299, filed January 31, 1997, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). Copies of documents AL2, AS4, AS7, AS13, and AR14 to AT14 are provided.

The Examiner's attention is directed to the following U.S. application:

U.S. Application No. 09/028,514, Gorfien *et al.*, filed February 23, 1998 (Document AS13); which is directed to related technical subject matter. The identification of this U.S. Patent Application should not be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

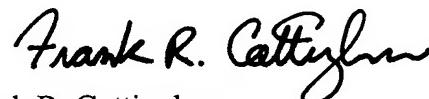
This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,  
Sterne, Kessler, Goldstein & Fox P.L.L.C.



Frank R. Cottingham  
Attorney for Applicant  
Registration No. 50,437

Date: June 9, 2004

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FORM PTO-1449 JUN 09 2004

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0942.3750002/RWE/FRCAPPLICATION NO.  
10/716,619FIRST NAMED INVENTOR  
Daley et al.FILING DATE  
November 20, 2003ART UNIT  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,673,649	06/16/1987	Boyce et al.			07/15/1983
	AB1	4,767,704	08/30/1988	Cleveland et al.			10/07/1983
	AC1	4,927,762	05/22/1990	Darfler et al.			11/30/1988
	AD1	5,024,947	06/18/1991	Inlow et al.			07/24/1987
	AE1	5,045,454	09/03/1991	Bertheussen			02/23/1990
	AF1	5,061,620	10/29/1991	Tsukamoto et al.			03/30/1990
	AG1	5,063,157	11/05/1991	Stockinger			01/11/1989
	AH1	5,122,469	06/16/1992	Mather et al.			10/03/1990
	AI1	5,128,259	07/07/1992	Morgan et al.			10/27/1989
	AJ1	5,316,938	05/31/1994	Keen et al.			12/18/1992
	AK1	5,336,614	08/09/1994	Brown et al.			08/14/1991

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 92/05246	04/02/1992	WIPO			Yes No
	AM1	WO 92/18615	10/29/1992	WIPO			Yes No
	AN1	WO 95/02685	01/26/1995	WIPO			Yes No
	AO1	WO 96/39487	12/12/1996	WIPO			Yes No
	AP1	WO 97/34999	09/25/1997	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Biddle, W., et al., "Cultivation and Ex Vivo Expansion of Human CD34+ Progenitor Cells Under Serum-Free Culture Conditions," in <i>Advances in Bone Marrow Purging and Processing: Fourth International Symposium</i> , Gee, A.P., et al., eds., Wiley-Liss, Inc., New York, pp. 351-361 (1994)
	AS	1	Biddle, W.C., et al., "Ex Vivo Expansion of Human Hematopoietic Progenitor Cells Under Serum-Free Conditions," in <i>Animal Cell Technology: Basic &amp; Applied Aspects</i> , Vol. 8, Funatsu, K., et al., eds., Kluwer Academic Publishers, Netherlands, pp. 25-40 (May 1997)
	AT	1	Bradley, T.R. and Metcalf, D., "The Growth of Mouse Bone Marrow Cells <i>In Vitro</i> ," <i>Aust. J. Exp. Biol. Med. Sci.</i> 44:287-300, University of Adelaide (1966)

EXAMINER

DATE CONSIDERED

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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 0942.3750002/RWE/FRC	APPLICATION NO. 10/716,619
		FIRST NAMED INVENTOR Daley et al.	
		FILING DATE November 20, 2003	ART UNIT 1632

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,371,010	12/06/1994	Brown et al.			02/08/1994
	AB2	5,342,777	08/30/1994	Cole et al.			03/03/1992
	AC2	5,359,046	10/25/1994	Capon et al.			12/09/1992
	AD2	5,397,706	03/14/1995	Correa et al.			08/06/1993
	AE2	5,405,772	04/11/1995	Ponting			06/18/1993
	AF2	5,472,867	12/05/1995	Kanz et al.			09/29/1993
	AG2	5,474,931	12/12/1995	DiSorbo et al.			09/21/1993
	AH2	5,556,954	09/17/1995	Burn et al.			12/15/1992
	AI2	5,573,937	11/12/1996	Shinmoto et al.			01/09/1995
	AJ2	5,599,705	02/04/1997	Cameron, R.B.			11/16/1993
	AK2	5,766,951	06/16/1998	Brown et al.			11/12/1992

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 97/33978	09/18/1997	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	2	Casadevall, N., et al., "Erythroid Progenitors in Polycythemia Vera: Demonstration of Their Hypersensitivity to Erythropoietin Using Serum Free Cultures," <i>Blood</i> 59:447-451, American Society for Hematology (1982)
AS	2	Civin, C.I., "Human Monomyeloid Cell Membrane Antigens," <i>Exp. Hematol.</i> 18:461-467, Elsevier Science Inc. (1990)
AT	2	Collins, P.C., et al., "Ex vivo culture systems for hematopoietic cells," <i>Curr. Opin. Biotech.</i> 7:223-230, Current Biology (April 1996)

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		FIRST NAMED INVENTOR Daley <i>et al.</i>	
		FILING DATE November 20, 2003	ART UNIT 1632

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	5,817,773	10/06/1998	Wilson <i>et al.</i>			02/23/1996
	AB3	5,879,940	03/09/1999	Torok-Storb <i>et al.</i>			05/23/1997
	AC3	5,945,337	08/31/1999	Brown <i>et al.</i>			10/17/1997
	AD3	6,103,529	08/15/2000	Price <i>et al.</i>			10/10/1997
	AE3	6,383,810	05/07/2002	Fike <i>et al.</i>			02/13/1998
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	3	Daley, J.P., <i>et al.</i> , "Ex Vivo Expansion of Human Hematopoietic Progenitor Cells in Serum-Free StemPro™-34 Medium," <i>Focus</i> 18:62-67, Life Technologies Inc (October 1996)
AS	3	Daniel, C.P. and Dexter, T.M., "The role of growth factors in haemopoietic development: Clinical and biological implications," <i>Cancer &amp; Metastasis Rev.</i> 8:253-262, Kluwer Academic (1989)
AT	3	de Wynter, E.A., <i>et al.</i> , "Comparison of Purity and Enrichment of CD34 <sup>+</sup> Cells from Bone Marrow, Umbilical Cord and Peripheral Blood (Primed for Apheresis) Using Five Separation Systems," <i>Stem Cells</i> 13:524-532, Karger (September 1995)

EXAMINER

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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>		FIRST NAMED INVENTOR <i>Daley et al.</i>	
		FILING DATE November 20, 2003	ART UNIT 1632

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FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	4	Dexter, T.M., et al., "Conditions Controlling the Proliferation of Haemopoietic Stem Cells <i>In Vitro</i> ," <i>J. Cell. Physiol.</i> 91:335-344, Wiley-Liss (1977)
AS	4	Drouet, X., et al., "Human liquid bone marrow culture in serum-free medium," <i>Brit. J. Haematol.</i> 73:143-147, Blackwell Scientific Publications (1989)
AT	4	Eaves, C.J., et al., "Methodology of Long-Term Culture of Human Hemopoietic Cells," <i>J. Tissue Cult. Meth.</i> 13:55-62, Tissue Culture Association (1991)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Eliason, J.F. and Odartchenko, N., "Colony formation of primitive hemopoietic progenitor cells in serum-free medium," <i>Proc. Natl. Acad. Sci. USA</i> 82:775-779, National Academy of Sciences (1985)
AS	5	Freshney, R.I., ed., in: <i>Culture of Animal Cells: A Manual of Basic Technique</i> , 2 <sup>nd</sup> Ed., Alan R. Liss, Inc., New York, NY, pp. 80-81 (1987)
AT	5	GIBCO BRL, Life Technologies™, 1993-1994 Catalogue and Reference Guide, Life Techonologies™, Inc., Gaithersburg, MD, pp. 1-2, 1-34, 1-38, 1-54, 1-70, 1-82, 1-99, 1-116, 4-43, 4-44, 4-45, 4-46, 4-59, 4-63, 5-3, and 5-4 (1993)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	6	Greenberg, H.M., et al., "Human Granulocytes Generated in Continuous Bone Marrow Culture are Physiologically Normal," <i>Blood</i> 58:724-732, American Society of Hematology (1981)
AS	6	Ham, R.G., "Clonal Growth of Mammalian Cells in a Chemically Defined, Synthetic Medium," <i>Proc. Natl. Acad. Sci. USA</i> 53:288-293, National Academy of Sciences (1965)
AT	6	Ham, R.G., "Formulation of Basal Nutrient Media," in: <i>Methods for Preparation of Media, Supplements and Substrata for Serum-Free Animal Cell Culture</i> , Barnes, D.W., et al., eds., Alan R. Liss, Inc., New York, NY, pp. 3-21 (1984)

EXAMINER

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	7		Haylock, D.N., et al., "Ex Vivo Expansion and Maturation of Peripheral Blood CD34 <sup>+</sup> Cells Into the Myeloid Lineage," <i>Blood</i> 80:1405-1412, American Society for Hematology (1992)			Yes No
	AS	7		Iscove, N.N., "Culture of Lymphocytes and Hematopoietic Cells in Serum-Free Medium," in: <i>Methods for Serum-Free Culture of Neuronal and Lymphoid Cells</i> , Barnes, D.W., et al., eds., Alan R. Liss, Inc., New York, NY, pp. 169-185 (1984)			Yes No
	AT	7		Koller, M.R. and Palsson, B.O., "Tissue Engineering: Reconstitution of Human Hematopoiesis Ex Vivo," <i>Biotechnol. &amp; Bioeng.</i> 42:909-930, Wiley Interscience (1993)			

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AN						Yes No
AO						Yes No
AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>8</u>	Lambert, K.J. and Birch, J.R., "Cell Growth Media," in: <i>Animal Cell Biotechnology</i> , Vol. 1, Spier, R.E. and Griffiths, J.B., eds., Academic Press, London, UK, pp. 85-123 (1985)
AS	<u>8</u>	Lebkowski, J.S., et al., "Serum-Free Culture of Hematopoietic Stem Cells: A Review," <i>Stem Cells</i> 13:607-612, AlphaMed Press (November 1995)
AT	<u>8</u>	Maurer, H.R., "Towards Chemically-defined, Serum-free Media for Mammalian Cell Culture," in: <i>Animal cell culture: a practical approach</i> , Freshney, R.I., ed., IRL Press, Oxford, UK, pp. 13-31 (1986)

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FOREIGN PATENT DOCUMENTS							
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	9	McAdams, T.A., <i>et al.</i> , "Hematopoietic cell culture therapies (Part I): cell culture considerations," <i>Trends Biotech.</i> 14:341-349, Elsevier Science Publishers (September 1996)
AS	9	Migliaccio, G., <i>et al.</i> , "The Biology of Hematopoietic Growth Factors: Studies in vitro under Serum-deprived Conditions," <i>Exp. Hematol.</i> 18:1049-1055, Elsevier Science Inc. (1990)
AT	9	Migliaccio, G. and Migliaccio, A.R., "Serum-Deprived Cultures of Primary Hematopoietic Cells," in: <i>Culture of Specialized Cells: Culture of Hematopoietic Cells</i> , Freshney, R.I., <i>et al.</i> , eds., Wiley-Liss, Inc., Somerset, NJ, pp. 81-98 (1994)

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FORM PTO-1449  <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 0942.3750002/RWE/FRC	APPLICATION NO. 10/716,619
		FIRST NAMED INVENTOR Daley <i>et al.</i>	FILING DATE November 20, 2003
		ART UNIT 1632	

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AL						Yes No
AM						Yes No
AN						Yes No
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AR	<u>10</u>	PCT Gazette, WO 98/00521, International Bureau of the World Intellectual Property Organization Under the Patent Cooperation Treaty, p. 275 (January 1998)
AS	<u>10</u>	Sandstrom, C.E., <i>et al.</i> , "Review: Serum-Free Media for Cultures of Primitive and Mature Hematopoietic Cells," <i>Biotechnol. &amp; Bioeng.</i> 43:706-733, Wiley Interscience (1994)
AT	<u>10</u>	Schain, L.R., <i>et al.</i> , "Animal Serum-Free Culture of Purified Human CD34+ Cells: Amplification of Progenitors from G-CSF and GM-CSF-Mobilized Peripheral Blood," <i>J. Hematother.</i> 6:335-349, Mary Ann Liebert, Inc. (August 1997)

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AR	11	Sigma® Chemical Co., "Tissue Culture Media and Reagents," in: <i>Sigma® Chemical Company Catalog</i> , Sigma® Chemical Co., St. Louis, MO, pp. 1142, 1470, and 1475 (1989)
AS	11	Sigma® Chemical Co., "Tissue Culture Media and Reagents," <i>Sigma® Chemical Company Catalog</i> , Sigma® Chemical Co., St. Louis, MO, pp. 1495, 1512, 1514, and 1516 (1994)
AT	11	Sonoda, Y., et al., "Analysis in serum-free culture of the targets of recombinant human hemopoietic growth factors: Interleukin 3 and granulocyte/macrophage-colony-stimulating factor are specific for early development stages," <i>Proc. Natl. Acad. Sci. USA</i> 85:4360-4364, National Academy of Sciences (1988)

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	AR	<u>12</u>	Steen, R., <i>et al.</i> , "c-kit Ligand Combined with GM-CSF and/or IL-3 Can Expand CD34 <sup>+</sup> Hematopoietic Progenitor Subsets for Several Weeks In Vitro," <i>Stem Cells</i> 12:214-224, Karger (1994)
	AS	<u>12</u>	"StemPro™-34 SFM," <i>Spectrum</i> , Life Technologies, Inc., p. 12 (May 1996)
	AT	<u>12</u>	Traycoff, C.M., <i>et al.</i> , "Rapid exit from G <sub>0</sub> /G <sub>1</sub> phases of cell cycle in response to stem cell factor confers on umbilical cord blood CD34 <sup>+</sup> cells an enhanced ex vivo expansion potential," <i>Exp. Hematol.</i> 22:1264-1272, Elsevier Science Inc. (1994)

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	AR	13	Zang, M., et al., "Production of Recombinant Proteins in Chinese Hamster Ovary Cells Using a Protein-Free Cell Culture Medium," <i>Bio/Tech.</i> 13:389-392, Nature Publishing Company (April 1995)				Yes No
	AS	13	Copy of Co-Pending United States Patent Application No. 09/028,514, Gorfien et al., filed February 23, 1998				Yes No
	AT	13	International Search Report for International Patent Appl. No. PCT/US97/01867, mailed June 5, 1997, European Patent Office, Netherlands				Yes No

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AR	14	Gruber D.F. and Jayme, D.W., "Cell and Tissue Culture Media: History and Terminology," in: <i>Cell Biology: A Laboratory Handbook</i> , Celis, J.E., ed., Academic Press, Inc., San Diego, CA, pp. 451-458 (1994)
AS	14	Ham, R.G. and McKeehan, W.L., "Media and Growth Requirements," <i>Meth. Enzymol.</i> 58:44-93, Academic Press (1979)
AT	14	Jayne, D.W. and Gruber, D.F., "Development of Serum-Free Media and Methods for Optimization of Nutrient Composition," in: <i>Cell Biology: A Laboratory Handbook</i> , Celis, J.E., ed., Academic Press, Inc., San Diego, CA, pp. 18-24 (1994)

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AR	15	Kohn, D.B., et al., "Engraftment of gene-modified umbilical cord blood cells in neonates with adenosine deaminase deficiency," <i>Nat. Med.</i> 1:1017-1023, Nature Publishing Company (October 1995)					
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